K052501

OCT 2 1 2005

510(k) SUMMARY
As required by the Safe Medical Devices Act of 1990

DESCRIPTION OF THE APPLICANT DEVICE

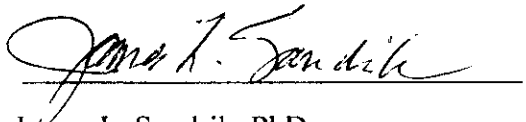
TRADE NAME: Multiple
COMMON NAME: Dentin/enamel adhesive
CLASSIFICATION NAME: Tooth resin bonding agent (21 CFR 872.3200, Product code KLE)

Cosmedent Resin Tooth Bonding Agent is a dual-cure 4th generation resin tooth bonding agent based on an acetone solution of room temperature polymerizing dimethacrylates. The device consists of two bottles designated as Primer A and Primer B. Primer A can be used alone and light cured, or it can be mixed with Primer B whereupon the adhesive will self cure in a clinically appropriate amount of time. In either case, two coats of the adhesive are applied to the prepared teeth. The adhesive bond strength of the device is approximately 25 MPa. The product is intended to be used to promote the adhesion of resin composite restoratives to dentin and enamel.

The technological characteristics of the applicant device are identical to the predicate device except with the latter; equal quantities of A and B are mixed and cured whereas with the former, A can be cured alone or mixed with B and allowed to self cure. The safety and efficacy are otherwise equivalent.

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

Bisco All-Bond 2 (K910860) is a dual-cure 4th generation resin tooth bonding agent based on an acetone solution of room temperature polymerizing dimethacrylates. Primers A and B are mixed and five coats of the mixed material are applied to the prepared teeth. The adhesive will self cure in a clinically appropriate amount of time, or the mixed adhesive can be light cured. The adhesive bond strength of the device is approximately 28 MPa. The product is intended to be used to promote the adhesion of resin composite restoratives to dentin and enamel.



James L. Sandrik, PhD

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Submitted: September 8, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

James L. Sandrik, PhD
Director of Regulatory Affairs
Cosmedent, Incorporated
401 North Michigan Avenue, Suite 2500
Chicago, Illinois 60611

Re: K052501
Trade/Device Name: Resin Tooth Bonding Agent
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: September 08, 2005
Received: September 13, 2005

Dear Dr. Sandrik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052501

Device Name: MULTIPLE (RESIN TOOTH BONDING AGENT)

Indications For Use:

Resin Tooth Bonding Agent is used to facilitate the adhesive bonding of restorative/preventive dental materials to dental hard tissues as well as to other restorative materials.

Resin Tooth Bonding Agent is marketed as a kit that may contain:

- A single light-cure resin component
- A two-component self-cure resin adhesive
- A phosphoric acid etchant
- A silane coupling agent

Prescription Use___X_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052501